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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,186	02/25/2004	Hugh S. West JR.	14000.8.1.1	2078

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EXAMINER
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KIM, JOHN

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/786,186	<b>Applicant(s)</b> WEST ET AL.	
	<b>Examiner</b> John Kim	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17,20 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17,20 and 25-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9, 11-13, 14, 15, 20, 25, 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 11-16 of copending Application No. 10/651671 ('671, Apparatus and methods for independently conditioning and pre-tensioning a plurality of ligament grafts during joint repair surgery, filed 8/29/03). Although the conflicting claims are not identical, they are not patentably distinct from each other because both describe using a tensioning device with a suture separator. The difference between this application claims and '671 application claims lies in the fact that '671 application claims include more elements with respect to the tension device and are thus more specific. Thus the invention of the '671

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application claims are in effect a "species" of the "generic" invention of the application claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are anticipated by the '671 application claims, they are not patentably distinct from the '671 application claims. Furthermore, specific claims from '671 application basically reads upon this application. For instance, '671 application claims 12-16 reads on this applications claims (in parenthesis): 12 (2, 3,15), 13 (4), 14 (9), 15, (5, 12, 18), and 16 (6, 7).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 14-17, 25-27, rejected under 35 U.S.C. 102(b) as being anticipated by Venturini et al (PCT Pub # WO 01/85042 which can be seen in US Pat 6749611, cited in office action dated 12/23/05).

Venturini discloses a suture separator with a body with proximal and distal sides, with guide passageways or recesses (8) to be attached to a graft tension device, and a

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means to separate sutures (passageways or recesses) (11) with a bone tunnel (middle 8) in the middle. In regards to claims 2 and 15, Venturini discloses the invention having a gripping head (3) and a chiseled end (5). In regards to claims 3 and 9, Venturini discloses having a plurality of attachment passages or recess which can partially be received with a post from a tension device. Regarding claims 4 and 11, Venturini teaches of having a first or second retention recesses or protrusions. Regarding claim 5, two of Venturini's inventions can be used in tandem to separate sutures. Regarding claim 6, two of Venturini's inventions, with the chisels ends facing in opposite directions, would form a recess (middle 8) for an interference screw can be inserted. Regarding claim 7 and 16, Venturini's invention has at least two surfaces. In regards to claim 8, Venturini shows that a first surface is substantially flat (see figure 1).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venturini et al (PCT Pub # WO 01/85042 which can be seen in US Pat 6749611, cited in office action dated 12/23/05) in view of Goble et al (US Pat 5713897, in IDS).

Venturini teaches of having a suture separator, but fails to disclose a graft tensioning device. Goble teaches of a ligament tensioning device that would apply a desired tensile load to one or more grafts. This allows proper tension applied to the graft upon insertion. It would have been obvious to one skilled in the art at the time the invention was made to construct the invention of Venturini in view of Goble in order to apply a proper tensile load to sutures, attached to a graft, with a suture separator to allow organization if there were a plurality of sutures.

### ***Response to Arguments***

Applicant's arguments filed 4/5/06 have been fully considered but they are not persuasive.

In regards to the provisional double patent rejection, the rejection still stands since it is noted the two applications have similar claims (a tension device with a suture separator). Thus, the two applications are not sufficiently divergent as applicant claims. The rejection still stands.

Applicant argues that the functional language added throughout the amended claims would overcome the rejection over prior art. As discussed in the personal and telephonic interview, examiner stressed the importance of defining applicant's invention with more structural limitations. It is acknowledged that functional language is as important as the structural limitations. However, while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. (See MPEP

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2114). If the functional language is silent in the prior art, then the examiner will determine if the prior art can inherently perform the claimed function. To establish inherency, extrinsic evidence must be presented. In this case, the extrinsic evidence is the structural similarity to the disclosed invention (*In re Schreiber*, 128 F.3d.1473, 44 USPQ2d 1429 (Fed Cir 1997)). Venturini does disclose the claimed invention in terms of structural limitations, as discussed above. Though it may be true the recesses of Venturini may not be able to separate the sutures after a certain load is applied to the sutures, it is not clearly claimed how applicant's recesses would prevent the same problem. No specific limitation was claimed in keeping the sutures in place; the applicant merely claims a recess or passageway which is clearly seen in Venturini invention. Hence, the rejection is proper and applicant's arguments are not found persuasive.

In response to Applicant's argument that Venturini's inventions has nothing to do with suture separation, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Applicant's arguments with respect to the rejection based on Jain and Filhol have been considered but are moot in view of the new ground(s) of rejection necessitated by applicant's amendments.

Applicant's arguments in regards to functional language is addressed above.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-2817. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JK 

  
EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER